



Louisiana Board of Pharmacy

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June 3, 2016

Senator John A Alario Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2016-1 ~ Controlled Dangerous Substance Prescriptions

Dear Senator Alario:

As we indicated in our first report to you on April 8, 2016, the Board is currently amending its rules to shorten the expiration date of prescriptions for controlled dangerous substances listed in Schedule II as well as to remove the restriction preventing the prescribing of controlled dangerous substances listed in Schedule II by physician assistants and optometrists. Both of these initiatives are responsive to legislative acts. Subsequent to our Notice of Intent published in the April 20, 2016 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on May 25, 2016.

We received no written comments or testimony prior to or during the public hearing. The Board has determined no revisions are necessary to the proposed rule as originally published, and further, determined it appropriate to move forward with the proposed rule.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the April 2016 Louisiana Register
- Summary of Comments from May 25, 2016 Public Hearing
- Full text of proposed rule

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule as a Final Rule in the July 20, 2016 edition of the Louisiana Register. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-HW@legis.la.gov
Editor, Louisiana Register – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health and Hospitals Board of Pharmacy

Controlled Substance Prescriptions (LAC 46:LIII.2525 and 2745)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend Chapter 25, Prescriptions, Drugs, and Devices as well as Chapter 27, Controlled Dangerous Substances, of its rules. In particular, the board intends to amend §2525, relative to the expiration date of prescriptions for controlled substances, in compliance with Act 865 of the 2014 Legislature, as well as §2745 to amend the list of practitioners authorized to prescribe controlled substances, in compliance with Act 453 of the 2015 Legislature.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter B. Prescriptions

§2525. Prescription Expiration

A. ...

B. A prescription for a controlled dangerous substance shall expire:

1. 90 days after the date of issue if the drug is listed in schedule II; or

2. six months after the date of issue if the drug is listed in schedule III, IV, or V.

C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, LR 42:

Chapter 27. Controlled Dangerous Substances

Subchapter F. Production, Distribution, and Utilization

§2745. Prescriptions

A. - A.1.c. ...

d. a physician assistant;

e. an advanced practice registered nurse;

f. an optometrist; or

A.1.g. - C.7.a.ii. ...

iii. The prescription form shall contain no more than four prescription drug or device orders. While nothing in these rules shall prohibit the pre-printing of any number of prescription drugs or devices on the prescription form, no prescription form issued by a prescriber shall identify more than four prescription drugs or devices to be dispensed.

iv. For each prescription drug or device ordered on a prescription form, there shall be a pre-printed check box labeled "Dispense as Written", or "DAW", or both.

v. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.

vi. The prescription form shall bear a single printed signature line, and the prescriber shall manually sign the prescription.

C.7.b. - G.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), LR 42:

Family Impact Statement

In accordance with section 953 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a Family Impact Statement on the Rule proposed for adoption, repeal, or amendment. The following statements are published in the *Louisiana Register* with the proposed agency Rule.

1. The effect on the stability of the family. We anticipate no effect on the stability of the family.

2. The effect on the authority and rights of parents regarding the education and supervision of their children. We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The effect on the functioning of the family. We anticipate no effect on the functioning of the family.

4. The effect on family earnings and family budget. We anticipate no effect on family earnings and the family budget.

5. The effect on the behavior and personal responsibility of children. We anticipate no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. We anticipate no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with section 973 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a Poverty Impact Statement on the Rule proposed for adoption, repeal, or amendment.

1. The effect on household income, assets, and financial security. We anticipate no impact on household income, assets, and financial security.

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no positive impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. We anticipate no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with section 965 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses.

1. The establishment of less stringent compliance or reporting requirements for small businesses. The proposed Rule does not exempt small businesses from compliance with any of the requirements.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no reporting deadlines in the proposed Rule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed Rule. The proposed Rule sets expiration dates for certain prescriptions, and further, identifies those practitioners eligible to prescribe certain prescriptions. The law did not provide for alternative options for small businesses.

5. The exemption of small businesses from all or any part of the requirements contained in the proposed Rule. There are no exemptions for small businesses.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a Provider Impact Statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities.

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. We anticipate no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The total direct and indirect effect on the cost to the provider to provide the same level of service. We anticipate minimal costs to the provider to implement the requirements of the proposed Rule.

3. The overall effect on the ability of the provider to provide the same level of service. We anticipate no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, May 25, 2016 at 9 a.m. in the board office. At

that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 p.m. that same day.

Malcolm J Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Controlled Substance Prescriptions

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule change will amend the expiration dates for certain prescriptions, and further, identify the practitioners eligible to prescribe controlled substances. The proposed rule change will result in a cost of approximately \$2,000 for printing costs. This includes \$1,000 for the proposed rule change in FY 16 and \$1,000 for the final rule in FY 17.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no impact on revenue collections of state or local governmental units from the proposed rule change.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The first section of the proposed rule change will shorten the existing expiration date for prescriptions written for controlled substances listed in Schedule II, from six months to three months. We anticipate no cost or benefit to individuals from that portion of the proposed rule change. The second section of the proposed rule change will remove existing limitations on prescriptions for controlled substances listed in Schedule II written by physician assistants and optometrists. To the extent those practitioners will now be able to write such prescriptions, there may be a positive economic benefit to those practitioners.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no impact on competition or employment.

Malcolm J. Broussard
Executive Director
1604#056

Evan Brasseaux
Staff Director
Legislative Fiscal Office



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Summary of Testimony & Public Comments
re
Regulatory Project 2016-1 ~ Controlled Substance Prescriptions
at
May 25, 2016 Public Hearing

No comments or testimony were received for this regulatory project.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

§2525. Prescription Expiration

- A. ...
- B. A prescription for a controlled dangerous substance shall expire:
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 - 2. Six months after the date of issue if the drug is listed in Schedule III, IV, or V.
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Chapter 27. Controlled Dangerous Substances

§2745. Prescriptions

- A. – A.1.c. ...
 - d. a physician assistant,
 - e. an advanced practice registered nurse,
 - f. an optometrist, or
- A.1.g – C.7.a.ii. ...
 - iii. The prescription form shall contain no more than four prescription drug or device orders. While nothing in these rules shall prohibit the pre-printing of any number of prescription drugs or devices on the prescription form, no prescription form issued by a prescriber shall identify more than four prescription drugs or devices to be dispensed.
 - iv. For each prescription drug or device ordered on a prescription form, there shall be a pre-printed check box labeled “Dispense as Written”, or “DAW”, or both.
 - v. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.
 - vi. The prescription form shall bear a single printed signature line, and the prescriber shall manually sign the prescription.
- C.7.b.i. – G.3. ...

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